THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

SYNTHON IP, INC.,	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 1:05cv1267**
	)	
PFIZER INC.,	)	
Defendant.	)	

FINDINGS OF FACT AND CONCLUSIONS OF LAW REGARDING INEQUITABLE CONDUCT CLAIM

In this patent infringement suit, plaintiff Synthon IP, Inc. alleged that a commercial process used by defendant Pfizer Inc. to manufacture the chemical compound amlodipine literally infringed two patents owned by Synthon, namely U.S. Patent No. 6,653,481 (the '481 patent), a process patent, and U.S. Patent No. 6,858,738 (the '738 patent), a derivative compound patent. From the outset, Pfizer denied infringement, contested the validity of the asserted patents, and alleged that Synthon had engaged in inequitable conduct in the course of the patents' prosecution, thereby rendering the asserted patents unenforceable. Just prior to trial, Synthon disclaimed seven of the eight claims of the '738 derivative compound patent and withdrew the remaining '738 claim from this case. The parties thus proceeded to trial solely on the '481 patent, on the basis of two alternative *Markman* definitions adopted for the primary claim phrase in dispute.[1] The seven-day trial culminated in a jury

[1] Following extensive briefing and oral argument, preliminary claim construction determinations issued pursuant to *Markman v. Westview Instruments*, 517 U.S. 370 (1996). The facts and reasons in support of these determinations were recorded in a Memorandum Opinion dated June 30, 2006. *See Synthon IP, Inc. v. Pfizer, Inc.*, 446 F. Supp. 2d 497 (E.D. Va. 2006) (*Synthon I*). Synthon thereafter sought reconsideration, leading to yet another round of briefing and argument, which in turn led to the decision to submit appropriate specific validity and

verdict in Pfizer's favor on all issues of infringement and validity of the '481 patent under both alternative claim phrase definitions. Thereafter, the matter proceeded to a two-day bench trial on Pfizer's inequitable conduct claim against Synthon — the only remaining substantive claim in the case.[2] Recorded here are the Court's findings of fact and conclusions of law on this inequitable conduct claim, issued in accordance with Rule 52, Fed. R. Civ. P.

FINDINGS OF FACT[3]

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infringement interrogatories to the jury with directions to answer each interrogatory twice, once on the basis of the claim constructions reflected in *Synthon I* and then again based on the second set of claim constructions akin to those advocated by Synthon. Thereafter, a post-verdict opinion issued resolving the issues raised in Synthon's motion for reconsideration and making clear for the record the final claim construction definitions applicable to this case. *See Synthon IP, Inc. v. Pfizer, Inc.*, 457 F. Supp. 2d 668 (E.D. Va. 2006) (*Synthon II*).

[2] Despite prevailing on all issues of infringement and validity at trial, Pfizer nonetheless sought to pursue its inequitable conduct claim in order "to constrain Synthon's efforts to continue harassing Pfizer with amlodipine-related patent litigation." In this regard, Pfizer contends, *inter alia*, that Synthon filed a divisional application of the '738 patent in March 2006 and sent a copy of that divisional application to Pfizer less than two weeks before the commencement of the jury trial in this case. In a letter attached to the divisional application, Synthon implied that additional patent infringement litigation would be pursued against Pfizer in the event Pfizer did not agree to take a license under the divisional application. Specifically, Synthon claimed in the letter (i) that "Pfizer's process for making amlodipine falls within the scope" of certain claims of the divisional application, (ii) that Synthon "believe[s] that infringement liability [by Pfizer] is inevitable" and (iii) that "it seems highly likely that this [divisional] patent application will grant before any possible design-around could be approved and implemented" by Pfizer. Significantly, Pfizer believes that a finding of inequitable conduct in this case would render not only the '481 and '738 patents unenforceable, but also any additional related or divisional patents, including the divisional application filed by Synthon in March 2006. *See, e.g., Fox Industries, Inc. v. Structural Preservation Systems, Inc.*, 922 F.2d 801, 804 (Fed. Cir. 1990) (recognizing that "a breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application"). In the circumstances, therefore, it is appropriate to address Pfizer's claim of inequitable conduct notwithstanding the jury verdicts in favor of Pfizer on validity and infringement.

[3] These findings of fact are based on testimony and evidence presented not only in the course of the two-day bench trial on inequitable conduct, but also during the seven-day jury trial on infringement and validity. References and citations to the transcript made herein will thus be

A. The Parties and Patents in Issue

1. Plaintiff Synthon IP, Inc. (Synthon) is a Virginia corporation with its principal place of business in Gainsville, Virginia. Synthon, a patent holding company, is one of several affiliated companies located throughout the world, including Synthon BV in the Netherlands and Synthon s.r.o. in the Czech Republic.

2. Defendant Pfizer Inc. (Pfizer) is a Delaware corporation with its principal place of business in New York, New York. Pfizer is the owner of U.S. Patent No. 4,572,909 (the '909 patent), a twenty-year old patent relating to the pharmaceutical compound amlodipine. Amlodipine is used in the management and treatment of hypertension and angina pectoris and is the active ingredient in Norvasc®, a well-known drug manufactured and sold by Pfizer.

3. On November 3, 2005, Synthon filed the instant patent infringement action against Pfizer, alleging that a commercial process used by Pfizer to manufacture amlodipine literally infringed certain claims of Synthon's '481 process patent and the derivative '738 compound patent. The '481 process patent, entitled "Process for Making Amlodipine," was issued by the Patent and Trademark Office (PTO) on November 25, 2003, to named inventors Theodorus Peters, Franciscus Benneker, Pavel Slanina and Jiri Bartl, all employees of Synthon's various affiliated companies. The derivative '738 compound patent, entitled "Process for Making Amlodipine, Derivatives Thereof, and Precursors Therefor," was subsequently issued by the PTO to these same four named inventors on February 22, 2005.

4. As set forth in the patents' essentially identical specifications, both the '481 and '738

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to volumes 1 and 2 of the bench trial transcript (BTT), or to volumes 1 through 7 of the jury trial transcript (JTT).

patents purportedly "relate[] to novel intermediates useful in the synthesis of amlodipine and related compounds as well as to processes of making and using the same." *See, e.g.*, '481 Patent Specification, col. 1, ll. 12-14. The '481 patent, in particular, is a 24-claim process patent relating to a synthetic process for making amlodipine using, *inter alia*, the "compound of formula (3)," one of the alleged "novel intermediates" or "new starting materials" referenced in the specification.[4] The '738 patent, a divisional of the '481 patent, is, by contrast, a product patent comprised of 8 claims directed at the "compound of formula (3)" itself.

5. Two of the four named inventors of the '481 and '738 patents — Benneker and Peters — were employed by Synthon BV in the Netherlands, while the remaining two — Slanina and Bartl — worked for Synthon s.r.o. in the Czech Republic. Benneker, in particular, was the chemist who performed the laboratory work leading to the alleged conception of the compound of formula (3) — the "new starting material" or "novel intermediate" claimed in the patents in issue. Peters, in turn, was a senior scientist on the Synthon amlodipine project who, together with Dr. Hans Hoorn from Synthon BV, supervised Benneker during various phases of the project. Slanina and Bartl, both from Synthon s.r.o., performed additional work on the amlodipine project under Hoorn's supervision beginning in mid-2000.

6. Prior to Benneker's laboratory work and alleged conception of the compound of formula (3), Hoorn conducted significant "literature research" pertinent to the Synthon amlodipine project.

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[4] *See, e.g.*, '481 Patent Specification, col. 1, ll. 12-14 (stating that "[t]he present invention relates to *novel intermediates* useful in the synthesis of amlodipine and related compounds as well as to processes of making and using the same") (emphasis added); *id.*, col. 3, ll. 42-45 (stating that "[i]t has now been discovered that phthalimidoamlodipine...can be prepared by a convenient method, with a good yield and purity, by employing *a new starting materia*[,] ...[namely] a compound having the formula (3)") (emphasis added); *id.*, col. 5, ll. 4-6 (noting that "[t]he present invention deals with *new* compounds...of formula (3)") (emphasis added).

JTT, vol. 4, pp. 9-10. He became the head of the chemical research and development group assigned to the amlodipine project in 1999 or 2000 and was thereby responsible for "coordination, project management type of activities, and the literature" pertaining to the project. JTT, vol. 4, p. 12. He was listed on Synthon's patent search reports pertinent to the amlodipine project and was a "member of the team" and a "conduit through which information was flowing" throughout the course of the project. BTT, vol. 1, p. 51. Indeed, Hoorn approved and signed each and every page of Benneker's earliest laboratory notebook documenting his work on the amlodipine project. Hoorn also shared an office with Peters, one of the named inventors and a senior scientist on the amlodipine project.

7. Benneker allegedly "c[a]me up with the idea" for using the compound of formula (3) in the amlodipine production process "[a]t the end of 1999." JTT, vol. 2, p. 33. His first laboratory attempt to make the compound of formula (3) on October 20, 1999, proved unsuccessful. Indeed, Benneker did not successfully make the compound of formula (3) until December 13, 1999. Because of this, the parties agreed, and the jury was instructed, that the date of conception for the asserted claims of the '481 patent was no earlier than December 13, 1999. Synthon thereafter first made amlodipine using the compound of formula (3) — the alleged "new starting material" or "novel intermediate" claimed in the patents in issue — in July or August of 2000.

B. Pfizer's DIA and SDD Publications

8. The record is unmistakably clear that the compound of formula (3) and its use in the amlodipine production process were not new when Synthon filed the '481 and '738 patent applications. Indeed, the record reflects that Pfizer has used the compound of formula (3) in its synthetic route for the production of amlodipine since at least 1992. The record is also clear, and the jury agreed, that this synthetic route, as well as the chemical structure of the compound of

formula (3), was disclosed by Pfizer in two prior art, "printed publications" within the meaning of 35 U.S.C. §§ 102(a) and (b).[5]

9. The first Pfizer prior art publication disclosing the compound of formula (3) and its use in making amlodipine is Dihydropyridines in Action (DIA), a sixteen-page booklet printed in 1989 by Hobsons Publishing PLC and authored by Dr. Fay Bendall with the assistance of Pfizer personnel. Page 10 of DIA illustrates Pfizer's "[p]roduction synthesis of amlodipine" and discloses both the chemical structure of the compound of formula (3), as well as its use in the synthetic route for the production of amlodipine.

10. The second Pfizer prior art publication disclosing the compound of formula (3) and its use in the amlodipine production process was Sandwich Drug Discoveries (SDD), a recruitment brochure published by Pfizer in several versions beginning in 1996 and distributed by Pfizer at recruiting events and symposia throughout Europe in the late 1990s. SDD highlights the structure and synthetic routes used to manufacture a number of pharmaceutical compounds discovered by

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[5] Sections 102(a) and (b) of the patent statute provide as follows:

> A person shall be entitled to a patent unless–
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> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States... .

35 U.S.C. §§ 102(a) and (b). A patent is therefore invalid as anticipated under § 102 if a single prior art reference discloses each and every limitation of the claimed invention. *See Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Pfizer scientists in Sandwich, England, including amlodipine. The amlodipine page from SDD, in particular, clearly depicts Pfizer's chemical process for the synthesis of amlodipine, including the use and chemical structure of the compound of formula (3). And, unlike DIA, SDD also discloses, *inter alia*, specific reagents used by Pfizer in the various stages of the amlodipine production process.

11. Prior to commencement of its amlodipine project and the filing of the '481 and '738 patent applications, Synthon personnel were aware of Pfizer's use of the compound of formula (3) in its amlodipine production process. Indeed, Synthon had in its files four copies of the SDD amlodipine page, two of which were in Hoorn's amlodipine "correspondence and reports" files, referred to in Dutch as "Maps." Specifically, Hoorn's "Map 1" contains documents from June 1998 to December 2000, in reverse chronological order, and the last page in the binder — meaning the first document placed in the binder — is the amlodipine page from the 1998 version of SDD. Hoorn also had in his files a second copy of the SDD amlodipine page containing a handwritten note stating, "To Pavel," referring to Pavel Slanina, one of the named inventors of the '481 and '738 patents. The third copy of the SDD amlodipine page was in Slanina's possession and included this same handwritten notation, "To Pavel," and the record reflects that Hoorn faxed this copy of the SDD amlodipine page to Slanina on June 5, 2000, just after Slanina began working on the Synthon amlodipine project. Finally, the fourth copy of the SDD amlodipine page was found in a "Literature" folder maintained by Arlette Vanderheijden, a manager on the Synthon amlodipine project.

12. In addition to the four copies of the SDD amlodipine page located in Synthon's files, Hoorn also had in his office a copy of the entire 1998 SDD brochure, with only the amlodipine page and the date page from the back of the brochure missing. Hoorn testified that he does not know

where, when or how he obtained that copy of SDD; he also does not know how a copy of the SDD amlodipine page ended up as the first document appearing in his "Map 1" correspondence and reports binder. Hoorn did, however, acknowledge that the SDD amlodipine page was "probably" a Pfizer document and that he had apparently faxed a copy of this document to Slanina in June 2000.

C. Synthon's OPIM and DLOC Documents

13. Synthon's "Chemical R&D Checklist" for its amlodipine project references numerous studies and documents prepared in the course of the project, including (i) an August 1999 document entitled "Overview of Potential Impurities and Metabolites Amlodipine besylate" (OPIM), and (ii) a July 1999 document entitled "Development List of Compounds Amlodipine" (DLOC).

14. The first of these Synthon documents — OPIM — states, in pertinent part, that "[t]he impurities mentioned in the monograph (Pharmeuropa vol. 10, No. 2 June 1998) and *a product folder from Pfizer (brandleader) suggest the following synthetic route* to ADP.bes [amlodipine besylate] to be most likely." (Emphasis added). Directly below this statement, OPIM depicts the precise chemical synthetic route disclosed on Pfizer's SDD amlodipine page, including the compound of formula (3) and its use in the amlodipine production process. In this regard, the synthetic route set forth in OPIM was what Peters — one of the named inventors of the '481 and '738 patents — "understood, as of September of 1999, to be Pfizer's most likely route of amlodipine besylate synthesis." JTT, vol. 3, p. 195.

15. Significantly, OPIM was signed and initialed by Hoorn and Peters in August 1999, months before Benneker allegedly "conceived" of the compound of formula (3), let alone performed any laboratory work related to the Synthon amlodipine project. Peters, however, disclaims any personal knowledge of either OPIM or the "product folder from Pfizer" referenced therein, testifying,

in pertinent part, as follows:

Q. ...Have you seen this document before, Dr. Peters?

* * *

A. Yes. I don't remember it, but my name is on it and I have signed it also.

* * *

Q. And did you create this document, Dr. Peters?
A. No.
Q. Do you know who did create the document?
A. Hans Hoorn. It says on the front page.

* * *

Q. ...That first page also mentions a product folder from Pfizer Brand Leader. What was that product folder?
A. I don't know.
Q. Do you know what was in the product folder?
A. No.
Q. But this was a product folder you had in September of '99; right?
A. Apparently...

* * *

Q. So that wouldn't be something from Synthon?
A. I would say it's from Pfizer because it says so.

JTT, vol. 3, pp. 194, 197. Hoorn, too, claims not to remember whether he personally prepared the portion of OPIM referencing "a product folder from Pfizer," although he did acknowledge that "[i]f the Pfizer product folder wasn't the page from Sandwich Drug Discoveries," then he could not say what else it could be or from where else it might have come. JTT, vol. 4, p. 40. In fact, no Synthon witness could identify any document other than SDD that might be the "product folder from Pfizer" referenced in OPIM. Benneker, for his part, recognized "that Sandwich Drug Discoveries is a Pfizer product folder," but he could not say whether it was the "product folder from Pfizer" mentioned in OPIM. JTT, vol. 2, p.65.

16. Another document prepared by Synthon personnel early in the course of its amlodipine project was DLOC. On the front page of this second document, Hoorn is identified as Head

Chemical R&D and Peters is identified as Senior Scientist, with separate spaces designated for the signatures and initials of each. From the face of the document, it appears DLOC was prepared in July 1999, prior to Benneker's alleged conception of the compound of formula (3). Yet again, DLOC, like OPIM, discloses the same synthetic route, compounds, and reagents as those identified in the SDD amlodipine page, including specifically the compound of formula (3).

17. No Synthon witness — including Hoorn and Peters whose names appear on the document — had any recollection of the preparation of DLOC; nor did they have any explanation of how the synthetic route that is disclosed in the SDD amlodipine page happened to be depicted in DLOC. Hoorn, in particular, testified that he has no memory of preparing DLOC, but he admitted that the synthetic route shown therein "was derived from publicly available literature," as opposed to any research or work Synthon had done on its own. JTT, vol. 4, p. 52. In other words, Hoorn acknowledged that the chemical structure of the compound of formula (3) and its use in the amlodipine production process was prior art that was available in the public domain.

18. Moreover, although a handwritten note included in Hoorn's "Map 1" correspondence and research binder questions whether "Route Pfizer" should be included in DLOC, Hoorn has no memory of making such a notation. In this regard, Hoorn specifically testified as follows:

> Q. But it refers to a Pfizer route and asking a question about whether to put the [Pfizer route] in the DLOC, right?
> A. I'm having problem with "a Pfizer." I don't know what you mean by that.
> Q. The Pfizer route.
> A. [I]t says here, "route Pfizer. Should I take it into the DLOC["].
> Q. Okay. And what Pfizer route were you referring to there?
> A. I don't remember.
>
> * * *
>
> Q. What Pfizer route did you put in the DLOC?
> A. I don't remember.

JTT, vol. 4, pp. 43-44.

19. Further, with respect to the fact that the same reagents that were disclosed in the SDD amlodipine page — sodium hydride (NaH) and tetrahydrofuran (THF) — were also reflected in DLOC, Hoorn testified as follows:

> Q. But you think you copied them either from Sandwich Drug Discoveries or from some other literature?
> A. I don't know. I don't know where these came from.
> Q. Well, did you come up with it yourself?
> A. I don't remember.
> Q. Did anyone at Synthon come up with it by his or herself?
> A. I don't know.
> Q. You don't have any knowledge that anyone independently at Synthon came up with that?
> A. No.

JTT, vol. 4, pp. 49-50.

20. Benneker likewise could not explain how the compound of formula (3) and its use to make amlodipine appeared in DLOC months before he allegedly "invented" it. On this issue, he simply testified as follows, providing no additional explanation:

> Q. And can you explain how Synthon wrote down the synthetic route before it actually did any chemistry in the lab?
>
> * * *
>
> A. I don't know.

JTT, vol. 2, p. 71.

D. Synthon's "Route According to Pfizer" Document

21. Benneker, Hoorn and Slanina each had a copy in their respective files of an additional document disclosing Pfizer's route for making amlodipine. This document, titled and referred to internally by Synthon employees as the "route according to Pfizer," shows the precise chemical synthetic route that is disclosed in the SDD amlodipine page, including the use of the compound of

formula (3) as an intermediate compound. Benneker — the alleged inventor of the compound of formula (3) — had "route according to Pfizer" saved on the C-drive of his computer. The record also reflects that Benneker emailed a copy of the "route according to Pfizer" document to the department secretary on August 17, 2000. Yet, at trial, Benneker testified that he did not "recall creating this document or sending this document." JTT, vol. 2, p. 80. Slanina, in turn, testified that he "can't recall it exactly." JTT, vol. 4, p. 188. Likewise, Hoorn testified that he did not know what the "route according to Pfizer" document was or how it got into his files. Hoorn also claimed not to recall ever having seen the "route according to Pfizer" document, although he acknowledged that his handwriting appeared on the face of the document.

E. The Prosecution History and Patent Infringement Litigation

22. On December 29, 2000, Synthon BV filed a provisional patent application with the PTO entitled "Process for Making Amlodipine and Precursors Therefor," naming as the inventors Benneker, Hoorn, Peters and Jacobus Lemmens. This application was written and prosecuted by Mark Buscher, Esq., who is now the president of Synthon, the owner of the patents in issue. The "Summary of Invention" contained in the provisional patent application stated, in pertinent part, that the invention related to "employing a new starting material," specifically the compound of formula (3), and "the use of the compound of the invention as an intermediate in the production of phtalimidoamlodipine and, consequently, in a production of amlodipine." Claim 1 of the provisional application was directed at the compound of formula (3) itself and additional claims were directed at the use of that compound to make phthalimidoamlodipine and ultimately, amlodipine.

23. In early 2001, shortly after filing the provisional application, Buscher interviewed Hoorn, Peters, Benneker, Slanina and Bartl. In the course of this meeting, Buscher reviewed the provisional

application with these and other Synthon representatives "claim by claim," including the claims directed at the alleged novel intermediate compound of formula (3). BTT, vol. 1, p. 68. Buscher, as he testified, did this in order to ascertain the identities of the specific "inventors" of each specific claim. Moreover, although Hoorn, Peters and Benneker were all "patent aware" and had "seen the patent process" previously, Buscher nonetheless reminded them of the duty of candor applicable to patent applications and of the importance of providing the PTO with any documents or information relevant to the applications. BTT, vol. 1, pp. 53-77. Thus, Buscher told the Synthon representatives in the course of the meeting that he "needed from them any information that was material to the patentability of the claims," stating specifically that if they had "a piece of prior art that disclosed the compound of formula (3), [he] wanted to know about it." *Id.*

24. In response to Buscher's inquiries in this regard, none of the named inventors or Synthon employees involved with the amlodipine project made any mention of the SDD amlodipine page contained in their files. Nor did they ever provide Buscher with a copy of OPIM, DLOC, or "route according to Pfizer," all of which depicted the precise chemical structure of the compound of formula (3) and its use in the amlodipine production process before Benneker allegedly conceived of the compound of formula (3).

25. On March 16, 2001, Synthon filed a patent application with the PTO, namely Application No. 09/809,351 (the '351 application), entitled "Process for Making Amlodipine, Derivatives Thereof, and Precursors Therefor." At the time of the filing, the named inventors were the same as those that had been listed in the provisional patent application — Benneker, Hoorn, Peters and Lemmens. Thereafter, on August 27, 2001, Synthon filed a continuing-in-part application under the same title, with no modifications made to the named inventors at that time. Both the

March and August 2001 applications referred to the compound of formula (3) as a "new starting material" and described therein the synthetic route for making amlodipine using the compound of formula (3) as an intermediate compound.

26. Sometime between the filing of the August 27, 2001 continuing-in-part application and January 2002, the named inventors listed in the patent application were altered. Specifically Hoorn and Lemmons were removed as named inventors and replaced with Slanina and Bartl. Thus, in January 2002, each of the four final named inventors — Peters, listed as the first inventor, Benneker, Slanina and Bartl — signed a "Combined Declaration and Power of Attorney for Utility Patent Application" swearing under oath,[6] *inter alia*, (i) that they were the "original, first and joint inventor[s]...of the subject matter which is claimed and for which a patent is sought on the invention," (ii) that they "reviewed and understand the contents of the...specification, including the claims," and (iii) that they "acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56."

27. Buscher also ensured that the named inventors fully understood the meaning and significance of the declaration that they signed in January 2002. On this issue, Buscher specifically testified as follows:

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[6] In this regard, immediately prior to the named inventors' signature lines, the declaration expressly provided as follows:

> I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements have been made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Q. Before you had the inventors sign this declaration, you communicated with each of them about what it was that they were declaring; right?
A. Yes.
Q. You explained to them what the declaration meant?
A. Yes.
Q. Including the duty to disclose material information?
A. Yes.

* * *

Q. Did you explain to them that they were declaring under oath that they were the original, first, and joint inventors of the subject matter that was claimed?
A. Yes.
Q. And that included the claim directed at the compound of formula (3); correct?
A. Yes.

* * *

Q. So each of the four inventors had reviewed the specification and the claims; is that right?
A. Yes.
Q. And you made sure that they understood that they were claiming the compound of formula (3); is that right?
A. I made sure they understood all of the claims they were claiming, yes. One of them was definitely the compound of formula (3).

BTT, vol. 1, p. 83-85.

28. At no stage in the prosecution did any of the Synthon applicants or inventors "mention[]...anything [to Buscher] about Pfizer having a synthesis route that used the compound of formula (3)." BTT, vol. 1, p. 76. Nor did anyone provide Buscher with a copy of SDD or any of the other documents in Synthon's files relating to Pfizer's use of the compound of formula (3) to make amlodipine. Specifically, neither Hoorn nor Slanina provided Buscher with a copy of the SDD amlodipine page contained in their files. Nor did Benneker, Hoorn or Slanina give Buscher a copy of "route according to Pfizer" that was in their files. Buscher likewise did not receive a copy of either DLOC or OPIM, both of which had been signed by Hoorn and Peters. Buscher was therefore

not aware of the "product folder from Pfizer" referenced in OPIM, or of Hoorn's handwritten note about whether to include "Route Pfizer" in DLOC. Likewise, although Benneker did inform Buscher in the course of the prosecution of the '481 and '738 patents "about the chemistry which is shown on ["route according to Pfizer"],...he didn't tell [him] that it was a Route According to Pfizer." BTT, vol. 1, p. 118. To the contrary, Benneker, at all times in the course of the prosecution, told Buscher that he himself had invented that synthetic route and the use of the compound of formula (3) in the amlodipine production process — an allegation that the jury did not accept in this case.

29. Sometime in 2002, in response to Synthon's request that Pfizer consider taking a license under Synthon's pending patent applications covering the compound of formula (3) and its use in making amlodipine, Pfizer alerted Buscher as to the existence of Pfizer's 1989 DIA publication. Specifically, Pfizer provided Buscher with a copy of the portion of DIA disclosing Pfizer's "production synthesis" of amlodipine and the use of the compound of formula (3) in that synthetic route and claimed that the invention of Synthon's application "lacked novelty." Buscher immediately recognized the materiality of the DIA document and promptly discussed the excerpt provided by Pfizer with Benneker and Peters. Yet again, at that time, neither Benneker nor Peters told Buscher about the similar information concerning Pfizer's use of the compound of formula (3) in its amlodipine production process that was then in their files, including the SDD amlodipine page, OPIM and DLOC.

30. On July 9, 2002, Buscher filed a "Supplemental Information Disclosure Statement" with the PTO, attaching thereto the two pages from DIA that Pfizer had provided to Buscher in response to Synthon's license inquiry. Buscher advised the patent examiner that he had received the DIA

excerpts from "a third party having an office in Great Britain,"[7] who had advised Buscher that DIA was published "sometime in the 1980's." The excerpts provided, however, did not disclose a precise publication date. Buscher further stated that he had neither received a complete copy of DIA from the third party, nor had he been able to locate the document through independent electronic database searches. At the end of the July 9, 2002 Supplemental Information Disclosure Statement, Buscher stated the following:

> Because Applicants cannot provide a complete copy of this document, nor the "publication date," and Applicants believe that this document is not a printed publication within the meaning of 35 U.S.C. § 102, it has not been listed on a PTO-1449 form. Nonetheless, pursuant to 37 C.F.R. § 1.56, Applicants wish to bring this information to the attention of the Examiner.

31. In September 2002, the patent examiner rejected claim 18 of the August 27, 2001 continuing-in-part application as being anticipated by several prior art references, namely Russian patent RU 21611156, Japanese patent JP 2001002677 and DIA. The rejected application claim 18 covered, in part, a process comprising reacting the compound of formula (3) with an alkyl 3-aminocrotonate to form a phtalimidoamlodipine, referred to in the application as the compound of formula (2).

32. In February 2003, Buscher filed an amendment to the patent application, arguing therein that the three references cited by the examiner in the rejection papers — namely the Russian patent, the Japanese patent and DIA — were not prior art to the application and thus did not anticipate application claim 18. To overcome the examiner's anticipation rejection, Synthon also submitted a "Rule 131 declaration" from the named inventors in order to establish an earlier invention date and

[7] Buscher did not specifically disclose that this third party was Pfizer.

thus "swear behind" the publication date of the Russian patent.[8] As required by the applicable federal regulations, the inventors' Rule 131 declaration referred only to rejected application claim 18. The Rule 131 declaration was signed by the named inventors between February 4 and 6, 2003.[9]

33. The patent examiner also cited Pfizer's '909 patent in the initial rejection papers. Synthon, in response, distinguished the '909 patent by arguing that it "does not convey carrying on a two-step reaction" and "does not disclose the structure of the applicants' compound of formula (3)." Significantly, the SDD amlodipine page, which was never provided to the patent examiner in the course of the prosecution, does convey such a two-step reaction process; it also clearly depicts the chemical structure of the compound of formula (3) — the alleged "new starting material" or "novel intermediate" claimed in the Synthon patent application.

34. In July 2003, the patent examiner issued a Notice of Allowability of all claims of what ultimately became the '481 patent, stating that the "Applicants'... declarations together with their remarks overcome the rejections of record." The examiner further recognized, erroneously, that "[t]he amended claim 18 distincts [*i.e.* is distinguishable] from the art of record in that the starting material [namely the compound of formula (3)] is novel," stating that "[a] process using a new

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[8] Title 37 C.F.R. 1.131 provides that "[w]hen any claim of an application...is rejected, the inventor of the subject matter of the rejected claim...may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference."

[9] The Rule 131 declaration averred that an experiment was performed by the named inventors of the '481 patent in the Czech Republic prior to the critical date applicable to the Russian patent. That experiment, according to the inventors, involved a "two-step reaction scheme," whereby in the first step, two starting materials are reacted to form an intermediate compound — the compound of formula (3) — and in the second step, "the formed intermediate...is reacted with methyl-3-aminocrotonate" to form an additional compound — the compound of formula (2) — elsewhere referred to as the "phthalodipine" or "phthalimidoamlodipine."

starting material is patentable."

35. Meanwhile, in May 2003, Synthon, with Buscher as the prosecuting attorney, filed a divisional patent application entitled "Process for Making Amlodipine, Derivatives Thereof, and Precursors Therefor," which application claimed priority from the December 29, 2000 provisional application and the March 16 and August 27, 2001 patent applications. And, like the earlier application, the May 2003 divisional application referred to the compound of formula (3) as a "new starting material." The claims set forth in the divisional application were directed only at the compound of formula (3), and with that divisional application the named inventors submitted another copy of their Rule 131 declaration. Shortly after the filing of the divisional application, in August 2003, Buscher sent Peters a letter stating, in pertinent part, that "[i]f you are aware of any other documents which might be relevant to the prosecution of this U.S. application, please forward them to us immediately so that [we] can file them in accordance with the duty of disclosure." Buscher received no documents or additional information in response to this letter request and the divisional application was ultimately allowed and issued by the PTO as the '738 derivative compound patent.

36. At no time during the prosecution of any of the applications for the '481 and '738 patents did the named inventors or anyone from Synthon disclose to the patent examiner either the SDD amlodipine page, "a product folder from Pfizer," "route according to Pfizer," or their knowledge about Pfizer's use of the compound of formula (3) to make amlodipine. Instead, the Synthon inventors consistently told the PTO that they had invented the compound of formula (3) and its use to make amlodipine. They included a claim directed at the compound of formula (3) itself in every single patent application and such a claim was ultimately allowed to issue as claim 1 of the '738 derivative compound patent.

37. In the summer of 2005, long after the '481 and '738 patents had issued, Buscher learned that Synthon's chemists were in possession of SDD and other "documents in the various files of Hoorn and Peters...that relate to [] Sandwich Drug Discoveries." BTT, vol. 1, p. 133. When he first saw the SDD amlodipine page, Buscher "recognized its materiality to the '481 and '738 Patents immediately." BTT, vol. 2, p. 20-21. And significantly, Buscher acknowledged in his testimony that he "probably" would not have sought a claim on the compound of formula (3) had he known about or learned of SDD in the course of the prosecution. BTT, vol. 1, pp. 63, 66.

38. In November 2005, Synthon filed a literal infringement action against Pfizer based on various asserted claims in the '481 and '738 patents. Both patents were pursued through discovery and required several *Markman* claim construction determinations. *See supra* n. 1. Yet, just before trial, Synthon disclaimed seven of the eight claims of the '738 derivative compound patent and withdrew the remaining '738 claim from this litigation case. Thus, on August 9, 2006, the matter proceeded to trial solely on the '481 patent, at the conclusion of which the jury found that Pfizer did not infringe any of the asserted claims of the '481 patent under either alternative claim phrase definition.[10] The jury also concluded — with respect to both alternative definitions — that all of the asserted claims were invalid on four grounds, specifically (i) anticipation by SDD and DIA under 35 U.S.C. § 102(a) and (b),[11] (ii) derivation from Pfizer's work under 35 U.S.C. § 102(f),[12] (iii) prior

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[10] The 17-page special verdict form was divided into four separate sections, namely (i) infringement under Alternative Definition #1, (ii) infringement under Alternative Definition #2, (iii) validity under Alternative Definition #1, and (iv) validity under Alternative Definition #2.

[11] In the course of the litigation, Synthon stipulated that SDD was a "printed publication" within the meaning of 35 U.S.C. §§ 102(a) and (b) and DIA, in turn, was deemed to be a printed publication as a matter of law. *See Synthon IP, Inc. v. Pfizer, Inc.*, 1:05cv1267 (E.D. Va. May 26, 2006) (Order); *Synthon IP, Inc. v. Pfizer, Inc.*, 1:05cv1267 (E.D. Va. June 30, 2006) (finding DIA to be a "printed publication" within the meaning of the patent statute given, *inter alia*, that

invention by Pfizer under 35 U.S.C. § 102(g),[13] and (iv) obviousness under 35 U.S.C. § 103.[14] Thereafter, a two day bench trial took place on October 23 and 24, 2006, on Pfizer's claim that Synthon had engaged in inequitable conduct before the PTO in the course of the prosecution of the '481 and '738 patents.[15] It is this remaining inequitable conduct claim that is at issue here.

CONCLUSIONS OF LAW

(i) Pfizer had received over 2000 copies of DIA from the publisher by November 1989 for distribution to its contacts and collaborators, (ii) hundreds of copies of DIA were kept by Pfizer in a cabinet in the chemistry department in Sandwich, England, for distribution to visitors and chemists as requested, (iii) DIA was provided by Pfizer employees to visitors, professors and students without restriction, (iv) the subject matter of DIA was used by various professors in the United Kingdom as a teaching tool for chemistry courses, workshops and seminars, (v) DIA was distributed by Pfizer employees during numerous recruiting visits in the late 1980s and early 1990s, (vi) DIA was cited by a professor in a 1992 edition of his textbook, *Heterocyclic Chemistry*, which was later translated into German and Spanish, and (vii) DIA was available in the reference section at the main library at the Open University in Milton Keynes, England).

[12] Section 102(f) provides that "[a] person shall be entitled to a patent unless...he did not himself invent the subject matter sought to be patented... ." 35 U.S.C. § 102(f).

[13] Section 102(g) provides, in part, that "[a] person shall be entitled to a patent unless...another inventor involved therein establishes...that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed... ." 35 U.S.C. § 102(g).

[14] Section 103 provides, in pertinent part, that

> [a] patent may not be obtained...if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a).

[15] Buscher was the only live witness at the two-day bench trial on Pfizer's inequitable conduct claim. As previously noted, Buscher is the current president of Synthon and served as the prosecuting attorney for the '481 and '738 patents. Buscher was employed as a patent examiner at the PTO from 1987 to 1991 and thereafter earned his law degree in 1994. He then began prosecuting patent applications for Synthon sometime in 1997 or 1998.

A. Duty of Candor

Applicants for patents have a duty "to prosecute patent applications in the PTO with candor, good faith, and honesty. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995) (citation omitted); *Semiconductor Energy Laboratory Co., Ltd. v. Samsung Electronics Co., Ltd.*, 4 F. Supp. 2d 477, 480 (E.D. Va. 1998) (*SEL I*), *aff'd*, 204 F.3d 1368 (Fed. Cir. 2000). And the duty of candor extends "throughout the patent's entire prosecution history." *Fox Industries*, 922 F.2d at 803; *Semiconductor Energy Laboratory Co., Ltd. v. Samsung Electronics Co., Ltd.*, 24 F. Supp 2d 537, 543 (E.D. Va. 1998) (*SEL II*), *aff'd* 204 F.3d 1368 (Fed. Cir. 2000). As noted in *SEL I*,

> [t]he vital importance of this duty [of candor] cannot be overstated. Without it, the edifice of patent law cannot stand. Indeed, the cornerstone presumption of an issued patent's validity, and the placement of the heavy burden on the infringer to show invalidity, both rest on the proper fulfillment of this duty.

SEL I, 4 F. Supp. 2d at 480.

The applicable federal regulations make clear that the duty of candor applies to "[e]ach individual associated with the filing and prosecution of a patent application... ." 37 C.F.R. § 1.56 (stating that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability"). And, in this context, the regulations define "[i]ndividuals associated with the filing or prosecution of a patent application" as including:

> (1) Each inventor named in the application;
> (2) Each attorney or agent who prepared or prosecutes the application; and
> (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

37 C.F.R. § 1.56; *see also Molins*, 48 F.3d at 1178 n.6 (recognizing that "the duty to disclose information material to patentability rests on the inventor, on each attorney or agent who prepares or prosecutes an application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application").

In this case, Buscher, as the prosecuting attorney, and each of the final named inventors — Peters, Benneker, Slanina and Bartl — had a duty of candor with respect to the '481 and '738 patents. *See* 37 C.F.R. § 1.56. Hoorn likewise owed a duty of candor in the course of the prosecution, not just because he was listed as a named inventor on the provisional and initial patent application, but also because he was "substantively involved" in the prosecution of the various related patent applications as well as the chemical research work underlying the applications. *See id.*; *see also Molins*, 48 F.3d at 1178 n.6. Indeed, Hoorn (i) was a member of the Synthon team working on the amlodipine project and the head of the group for a period of time, (ii) conducted literature research pertaining to the project, (iii) participated in the preparation of OPIM and DLOC, and (iv) received the patent search reports related to the Synthon amlodipine project. Hoorn also participated in detailed discussions with Buscher, Benneker and Peters about the patent applications that ultimately led to the issuance of the '481 and '738 patents, and during those discussions, Hoorn was reminded of his duty of candor and asked to turn over all information relevant to the pending patent applications.

Accordingly, the record reflects that at least six individuals — namely Buscher, Hoorn, Peters, Benneker, Slanina and Bartl — were subject to the duty of candor required by 37 C.F.R. § 1.56 in the course of the prosecution of the '481 and '738 patents.

B. Inequitable Conduct

It is settled that a breach of the "duty of candor, good faith, and honesty constitutes inequitable conduct, and renders all claims of the patent involved unenforceable." *SEL I*, 4 F. Supp. 2d at 480 (citing *Molins,* 48 F.3d at 1178); *see also Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1186 (Fed. Cir. 2006); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd.*, 394 F.3d 1348, 1351 (Fed. Cir. 2005). Such impermissible inequitable conduct includes, *inter alia*, "affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." *Molins*, 48 F.3d 1178.

The inequitable conduct determination requires a two-step analysis. *SEL I*, 4 F. Supp. 2d at 481 (citing *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1439 (Fed. Cir. 1991)). Thus, the party raising the affirmative defense of inequitable conduct — in this case Pfizer — must prove by clear and convincing evidence that a named inventor, prosecuting attorney or agent, or other individual substantively involved in the preparation or prosecution of the patent application (i) failed to disclose material prior art or other information and (ii) that they did so with the intent to deceive the PTO. *See ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998); 37 C.F.R. § 1.56. And significantly, each prong of this two-part analysis — both materiality of the undisclosed information and intent to deceive — must be proven by clear and convincing evidence. *See, e.g., Union Pacific Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001); *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988) (en banc).

C. Materiality

With respect to the first prong of the inequitable conduct test, it is well-settled that information is "material" under 37 C.F.R. § 1.56(b) when "there is a substantial likelihood that a

reasonable Examiner would have considered the information important in deciding whether to allow the application to issue as a patent." *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1326-27 (Fed. Cir. 2000); *see also* 37 C.F.R. § 1.56(b). More specifically, materiality is defined in 37 C.F.R. § 1.56 as follows:

> (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.[16]

37 C.F.R. § 1.56(b). Thus, "materiality is phrased in terms of whether a misrepresentation, if corrected, or an omitted reference, if disclosed, would, itself or together with other information, give rise to a *prima facie* (*i.e*. rebuttable) case of unpatentability...[and] [i]f so, the omitted reference or misrepresentation is material'" *SEL I*, 4 F. Supp. 2d at 482. And significantly, "[a] finding that a withheld reference anticipates a claim in a patent satisfies the most stringent standard of materiality." *Fox Indus.*, 922 F.2d at 804. An "omitted reference or misrepresentation may also be material if it refutes or is inconsistent with the applicant's patentability arguments." *SEL I*, 4 F. Supp. 2d at 482; *see also Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997).

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[16] Prior to 1992, Rule 56 defined materiality as "a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56 (1991). Although this definition was expanded to its current form in 1992, this amendment did not supplant then-established Federal Circuit precedent concerning the materiality standard. *See Ferring*, 427 F.3d at 1187 n.6.

It is also important to note that information is not material when it is "merely cumulative of references that were already before the examiner." *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1378 (Fed. Cir. 2001); *accord LNP Eng'g Plastics, Inc. v. Miller Waste Mills*, Inc., 275 F.3d 1347, 1360 (Fed. Cir. 2001). Yet, a reference is not cumulative if it contains information or features not found in the prior art of record. *See LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) (stating that "MS107 could not possibility be cumulative with respect to a feature not found in any disclosed prior art"); *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1374 (Fed. Cir. 2000) (affirming that a reference was not cumulative because it "contained a more complete combination of the elements claimed in the '636 patent than anything else before the PTO"). Information also is not cumulative when an argument made during prosecution could not have been made had that information been disclosed. *See Bruno*, 394 F.3d at 1353 (finding prior art was not cumulative because "[h]ad the examiner known about the Wecolator...Bruno could not have touted the front offset swivel as a point of novelty").

Here, the record reflects that the Synthon applicants, throughout the entire course of the prosecution, misrepresented to the PTO that the compound of formula (3) was "new," "novel" and their own invention. And, despite repeated requests and reminders about the duty of candor from Buscher, the named inventors and Hoorn likewise failed to disclose information to the PTO that was in their possession, including the SDD amlodipine page, showing that Pfizer had been using the compound of formula (3) to make amlodipine for years. Moreover, these misrepresentations and nondisclosures on the part of the Synthon applicants were highly material within the meaning of 37 C.F.R. § 1.56, as such misrepresentations and withheld information were essential to the question

of patentability. Indeed, Synthon sought claims directed to the compound of formula (3) itself, and to its use to make amlodipine. The applicants could not have sought those claims or made the statements they did regarding the compound of formula (3) being "new" and "novel" and their own invention had they disclosed to the PTO that the compound of formula (3) was actually invented and used by Pfizer. Likewise, when Buscher ultimately saw SDD, he immediately recognized that it was material to the asserted claims, noting that he "understood that what was shown on [the route according to Pfizer] document was precisely what [Synthon was] claiming in [its] patent application." BTT, vol. 1, p. 76. He further admitted that he "probably" would not have sought any claims covering the compound of formula (3) had he known about SDD and the materials in Synthon's files in the course of the prosecution. BTT, vol. 1, pp. 63, 66. To be sure, Synthon ultimately disclaimed all but one of the claims of the '738 patent in light of its stipulation that SDD is indeed a prior art, printed publication within the meaning of the patent statute. *See* 35 U.S.C. §§ 102(a) and (b). And, the jury found by clear and convincing evidence (i) that Synthon derived its inventions from Pfizer's earlier work and (ii) that SDD anticipated the asserted claims in the '481 patent.

And, contrary to Synthon's arguments, the undisclosed knowledge of Pfizer's synthetic route for the production of amlodipine using the compound of formula (3), including specifically the SDD amlodipine page, was not cumulative to DIA or any of the other information already before the PTO. Indeed, in the applicants' response to the examiner's initial rejection of application claim 18, Buscher effectively eliminated the Russian Patent, the Japanese Patent and DIA[17] as potential prior

[17] It should also be noted that Buscher, and ultimately the PTO, learned of the existence of DIA not through anyone at Synthon, but rather through Pfizer.

art references. With respect to the DIA excerpt, in particular, Buscher argued not that it was immaterial, but, *inter alia*, that it was not a printed publication within the meaning of the patent statute; the examiner presumably accepted this argument as the initially rejected claim was allowed to issue. Thus, once Buscher "eliminated those three pieces of prior art, there was no art before the examiner which showed the structure of the compound of formula (3)." BTT, vol. 2, p. 17. Thus, disclosure of SDD and of Pfizer's use of the compound of formula (3) in its amlodipine production process would not have been cumulative to the information already presented to the PTO.[18] Indeed, the SDD amlodipine page is a prior art reference that, unlike any other prior art reference before the examiner, specifically disclosed the compound of formula (3), its use in the amlodipine production process, as well as various reagents used in the course of that process. Not only does SDD include additional features not disclosed in DIA, but Synthon actually stipulated that SDD, as opposed to DIA, was a printed publication within the meaning of the patent statute. *See Synthon IP, Inc. v. Pfizer, Inc.*, 1:05cv1267 (E.D. Va. May 26, 2006) (Order).

SDD also is not cumulative for the additional reason that certain arguments made by Synthon in the course of the prosecution could not have been made had SDD been disclosed to the PTO. *See Bruno*, 394 F.3d at 1353. In this regard, during the course of the prosecution of the '481 patent, Synthon distinguished Pfizer's earlier '909 patent on the ground that it "does not convey carrying on a two step reaction" and "does not disclose the structure of applicants' compound of formula (3)."

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[18] Synthon's argument that SDD is not material because it does not disclose the isolating limitation added to the '481 patent claims during prosecution is without merit, as inequitable conduct cannot be cured through a fortuitous amendment of claims. *See Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1331 (Fed. Cir. 1998); *SEL II*, 24 F. Supp. 2d at 544-45. Equally fatal to this argument is the fact that the jury in this case found by clear and convincing evidence that the asserted claims, including the "isolating" step, were anticipated by SDD and derived from Pfizer's earlier work.

SDD, however, does precisely that; that is, SDD discloses both a two step reaction and the structure of the compound of formula (3). Likewise, SDD also contradicts the applicants' representations to the PTO that they had invented the "new" and "novel" compound of formula (3). Simply put, had Synthon disclosed SDD to the PTO, it could not have made the arguments it did in the course of the prosecution. *See Bruno*, 394 F.3d at 1353 (finding prior art was not cumulative because "[h]ad the examiner known about the Wecolator, however, Bruno could not have touted the front offset swivel as a point of novelty").

Thus, in summary, the Synthon applicants misrepresented to the PTO that they had invented the compound of formula (3) and its use in making amlodipine when they knew they had not. They then withheld all of the information from the PTO that would have revealed that misrepresentation, including the SDD amlodipine page then in their files. The record reflects clearly and convincingly that the misrepresentations and withheld information in this regard were highly material and not cumulative of other information before the PTO. In other words, the misrepresentations and nondisclosures "were central to the essential question of patentability" sufficient to meet the materiality prong of the inequitable conduct test. *SEL I*, 4 F. Supp. 2d at 496.

D. Intent to Deceive

The second prong of the inequitable conduct test — intent to deceive the PTO — "is an independent element of inequitable conduct in patent prosecution, and must be separately established" by clear and convincing evidence. *Hupp v. Siroflex of Am., Inc.*, 122 F.3d 1456, 1465 (Fed. Cir. 1997). In this regard, the party asserting inequitable conduct must make a threshold showing of intent to deceive the PTO. Important to this analysis is the fact that materiality of the information withheld does not presume intent. *See Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438

F.3d 1123, 1134 (Fed. Cir. 2006) (stating that "[i]ntent to deceive...cannot be 'inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent") (quoting *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996); *Allen Engineering Corp. v. Bartell Indus.*, 299 F.3d 1336, 1351-52 (Fed. Cir. 2002)).

As a practical matter, "intent need not, and rarely can, be proven by direct evidence." *Ferring*, 437 F.3d at 1191 (quoting *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989)); *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1189 (Fed. Cir. 1993). Indeed, "[d]irect evidence of intent or proof of deliberate scheming is rarely available in instances of inequitable conduct, but intent may be inferred from the surrounding circumstances." *Critikon*, 120 F.3d at 1256 (citation omitted). Thus, as explained in *SEL I*:

> The test [for intent] requires a consideration of, and a judgment on, the totality of the circumstances. In the words of the Federal Circuit, courts must determine whether the conduct "in its totality manifests a sufficiently culpable state of mind to warrant a determination that it was inequitable." This sensible formulation recognizes that direct proof of intent is rarely available and that it is impossible to scrutinize directly the workings of the human mind.

SEL I, 4 F. Supp. 2d at 482 (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

It is clear that evidence of good faith must be considered in determining whether a patentee intentionally deceived the PTO. *See Purdue Pharma.*, 438 F.3d at 1134; *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1330 (Fed. Cir. 1998). Yet, it is equally clear that "[a] mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice in such circumstances." *Critikon*, 120 F.3d at 1257. It is also significant to note that the duty of candor cannot be avoided by willful ignorance or compartmentalization of knowledge within a company in

an effort to insulate the patent applicants and their attorneys from information unfavorable to patentability.[19] So, too, patent applicants cannot avoid the duty of candor by failing to disclose material information to their lawyer or the prosecuting attorney. *See Novo Nordisk Pharms., Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 1361-62 (Fed. Cir. 2005) (rejecting the "circular logic" that failure of counsel to disclose the facts was excused "because the inventors failed to fully inform them" of those facts). Indeed, as recently stated in *In re Metoprolol Succinate Patent Litigation*, 2006 WL 120343, at *25 (E.D. Mo. Jan. 17, 2006):

> Although Astra's United States patent counsel...believed he made all of the disclosures necessary, Astra failed to provide him with important and material information...[and] Astra cannot benefit from its failure to disclose material information to its United States patent counsel and then hide behind its argument that he acted in good faith and candor in his prosecution of the patent.

It is also important to note that "[a]s a general principle, materiality and intent are balanced — a lesser quantum of evidence of intent is necessary when the omission or misrepresentation is highly material, and vice versa." *Amgen*, 314 F.3d 1358. In other words, "the more material the omission [or misrepresentation], the less culpable the intent required... ." *SEL I*, 4 F. Supp. 2d at 481

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[19] *See FMC Corp. v. Hennessy Industries, Inc.*, 836 F.2d 521, 526 n.6 (Fed. Cir. 1987) (recognizing in the context of an alleged infringer's inequitable conduct claim that "one should not be able to cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that information or prior art"); *see also Ranbaxy Laboratories Ltd. v. Abbott Laboratories*, 2005 WL 3050608, at *8 (N.D. Ill. Nov. 10, 2005) (where plaintiff argued that defendant was foreclosed from preliminary injunctive relief because defendant had engaged in inequitable conduct before the PTO, the district court found two of defendant's patents preliminarily invalid based on defendant's intentional failure to disclose highly material information to the PTO in the course of the prosecution, thereby rejecting defendant's argument that "would permit a company to conduct sweeping studies of an invention, compartmentalize the results in separate divisions, and then submit only discrete portions to the PTO in support of specific claims while claiming ignorance of other, potentially highly material information, because that information was in a different compartment").

(quoting *Halliburton*, 925 F.2d at 1439); *see also GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1273 (Fed. Cir. 2001).

Finally, the defense of inequitable conduct is ultimately an equitable remedy for the trial court to decide. *See Kingsdown*, 863 F.2d at 876. Thus, if the moving party establishes both materiality and deceptive intent by clear and convincing evidence, the trial court must still consider whether equity warrants rendering the patent unenforceable. *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 1001 (Fed. Cir. 2000); *ATD*, 159 F.3d at 546-47. In other words, "[u]pon finding evidence that satisfies a threshold measure of materiality and intent, the trial court then weighs that evidence to determine that the equities warrant a conclusion of inequitable conduct." *Agfa Corp. v. Creo Prods., Inc.*, 451 F.3d 1366, 1377 (Fed. Cir. 2006). The trial court must therefore "weigh[]...the materiality and intent in light of all the circumstances to determine whether the applicant's conduct is *so culpable* that the patent should be held unenforceable." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed. Cir. 2003) (emphasis in original) (citations omitted). And, in all cases, "[a] determination of inequitable conduct is committed to a district court's discretion." *Critikon v. Becton Dickinson Vascular Access*, 120 F.3d 1253, 1255 (Fed. Cir. 1997).

Here, the evidence makes unmistakably clear that Buscher, as the prosecuting attorney, did not act with the intent to deceive the PTO at any time in the course of the prosecution of the '481 and '738 patents. Indeed, there is no evidence in the record that Buscher intentionally withheld from the patent examiner any information pertinent to the patent applications <u>of which he was aware</u>. To the contrary, at no stage in the course of the prosecution did any of the Synthon applicants or inventors "mention[]...anything [to Buscher] about Pfizer having a synthesis route that used the compound of

formula (3)." BTT, vol. 1, p. 76. Nor did anyone provide Buscher with a copy of SDD or any of the other documents in Synthon's files revealing Pfizer's use of the compound of formula (3) to make amlodipine, including OPIM, DLOC or "route according to Pfizer." Buscher repeatedly reminded Hoorn and the named inventors in the course of the prosecution of the duty of candor applicable to patent applications and of the importance of providing the PTO with any documents or information relevant to the applications. BTT, vol. 1, pp. 53-77. Buscher also told Hoorn, Peters, Benneker and Slanina that he "needed from them any information that was material to the patentability of the claims," stating specifically that if they had "a piece of prior art that disclosed the compound of formula (3), [he] wanted to know about it." *Id.* Moreover, Buscher, when provided with an excerpt from DIA from Pfizer in the course of the prosecution, promptly disclosed that excerpt to the patent examiner in a "Supplemental Information Disclosure Statement." In sum, Buscher's good faith and fulfillment of the duty of candor in the course of the prosecution is well documented in the record and a finding of inequitable conduct based on Buscher's failure to disclose the SDD amlodipine page or other material information to the PTO is not warranted in the circumstances.

The same cannot be said of Hoorn and the named inventors. In this regard, it should first be noted that Buscher's apparent good faith in the course of the prosecution cannot serve to insulate Hoorn and the named inventors from a finding of deceptive intent in this instance. Here, the evidence shows clearly and convincingly that, at the very least, Hoorn, Benneker and Peters (i) copied what they knew to be Pfizer's work, (ii) put that work into various Synthon documents and ultimately a patent application, and (iii) swore to the PTO that it was their own invention.[20] They

[20] Consistent with this, the jury found by clear and convincing evidence that Pfizer's

then failed to disclose to Buscher, the prosecuting attorney, information highly material to the claimed invention — indeed information that would make clear to the patent examiner that the compound of formula (3) was not "new" and "novel" as alleged in the patent application. Clearly Hoorn and the named inventors cannot sidestep the duty of candor by failing to disclose this material information to the prosecuting attorney and then hide behind the prosecuting attorney's lack of knowledge of such material information.[21]

Significantly, no Synthon representative has offered any explanation whatsoever for how it happened that every single document that would have exposed Pfizer's prior use of the compound of formula (3) in its amlodipine production process, including specifically SDD, was withheld from the PTO in the course of the prosecution of the '481 and '738 patents. To the contrary, Hoorn, Benneker, Peters and Slanina all claim not to recall any of the pertinent documents disclosing the fact that the compound of formula (3) was not "new" and "novel" as they had represented to the PTO, but rather had been used by Pfizer for years in the amlodipine production process. This is so despite the fact that all of these pertinent documents — including OPIM, DLOC, SDD and "route according to Pfizer"— were either prepared by, signed by, and/or located in the files of the precise Synthon representatives who owed a duty of candor to the PTO in this case.

Viewed in the totality of the circumstances, this across-the-board lack of recollection on the

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invention "was communicated to one or more of the named inventors before the Synthon inventors made their invention." *See Synthon IP, Inc. v. Pfizer, Inc.,* 1:05cv1267 (E.D. Va. 2006) (Special Verdict Form).

[21] *See Novo Nordisk*, 424 F.3d at 1361-62 (Fed. Cir. 2005) (rejecting the "circular logic" that failure of counsel to disclose the facts was excused "because the inventors failed to fully inform them" of those facts); *In re Metoprolol*, 2006 WL 120343, at *25 (recognizing that a patent applicant cannot benefit from its failure to disclose material information to its patent counsel and then "hide behind its argument that he acted in good faith and candor in his prosecution of the patent").

part of the relevant Synthon employees is simply not credible, particularly given the significance and obvious materiality of the documents in issue. In other words, given the degree to which the compound and chemical process claimed in the '481 and '738 patent applications were based on the compound of formula (3) and its use in the amlodipine production process, there can be no reasonable doubt that Hoorn and the named inventors were aware of the significance of SDD and acted knowingly in failing to disclose that material prior art publication to the PTO.[22] This conclusion is buttressed by the fact that the compound of formula (3) and the precise chemical route disclosed in SDD appeared in multiple internal Synthon documents, including OPIM, DLOC and "route according to Pfizer."

It should also be noted that the various Synthon representatives, including Hoorn, Peters, Slanina and Benneker, testified only that they did not recall the pertinent documents — namely OPIM, DLOC, SDD and "route according to Pfizer" — at the time they provided their testimony in this case. Significantly, they did not testify, and indeed there is nothing in the record, as to their recollection or knowledge of those documents during the course of the prosecution of the '481 and '738 patents — the critical time frame for the instant inequitable conduct analysis. Nor did Hoorn, Peters, Slanina and Benneker offer any good faith explanation for their failure to disclose SDD to the PTO in the course of the prosecution of the '481 and '738 patents. Indeed, the lack of any

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[22] *See Bruno*, 394 F.3d at 1353 (recognizing that where the patentee "has not proffered a credible explanation for the nondisclosure...an inference of deceptive intent may be fairly drawn in the absence of such an explanation," noting that "[n]ormally, it can be expected that an innocent party will be motivated to try to present convincing reasons for its actions or inaction"); *Baxter*, 149 F.3d at 1330 (in upholding the district court's determination that two patents were unenforceable due to the inventors' failure to disclose a prior art device that "formed the basis" for the inventions, the Federal Circuit recognized that "given the degree to which the patented inventions were based upon the [prior art device]...an inference that the inventors were aware of its importance is justified").

credible explanation for the nondisclosure of this highly material information is highly probative of deceptive intent.[23] And, Synthon's "mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice" to overcome such a finding this case. *Critikon*, 120 F.3d at 1257.

Nor is this a case where the lack of a good faith explanation for not disclosing material information to the PTO is the only evidence supporting a finding of deceptive intent.[24] To the contrary, it is this lack of a credible, good faith explanation on the part of Hoorn and the named inventors, combined with various additional factors present in the case, that lead clearly and convincingly to the conclusion that Synthon intended to deceive the PTO in the course of the

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[23] *See Ferring*, 437 F.3d at 1191 (recognizing that summary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding"); *Bruno*, 394 F.3d at 1354 (noting that "in the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information"; *Critikon*, 120 F.3d at 1257 (stating that "a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality , can expect to find it difficult to establish 'subjective good faith' sufficient to prevent the drawing of an inference of intent to mislead").

[24] *See M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335 (Fed. Cir. 2006), where the Federal Circuit stated as follows:

> The only evidence that the district court relied upon in its determination that Astro intended to deceive the PTO was Astro's failure to offer a good faith explanation of its nondisclosure of the Model 220. To be sure...the absence of such an explanation can constitute evidence supporting a finding of intent. When the absence of good faith is the only evidence of intent, however, that evidence alone does not constitute clear and convincing evidence warranting an inference of intent.

Id. at 1341.

prosecution of the '481 and '738 patents. Such additional factors include:

(i) the fact that the materiality of the undisclosed information is plain on its face — indeed the SDD amlodipine page discloses the precise synthetic route claimed in Synthon's patent application, including the use of the compound of formula (3), thus making unmistakably clear that the compound of formula (3) was not "new" or "novel" as claimed in the patent application;

(ii) the fact that Pfizer's prior use of the compound of formula (3) in its amlodipine production process had been the subject of "substantial documentation and internal discussions" amongst Synthon employees, including Hoorn and the named inventors, and was fully documented in numerous internal Synthon documents — including OPIM, DLOC and "route according to Pfizer" — long before Benneker allegedly conceived of the compound of formula (3);[25]

(iii) the substantial quantity of separate documents located in Synthon's files disclosing Pfizer's prior use of the compound of formula (3) in its amlodipine production process, some of which included handwritten notes from members of the Synthon amlodipine team, particular Hoorn;

(iv) the fact that disclosure of the SDD amlodipine page showing Pfizer's use of the compound of formula (3) in its amlodipine production process would have precluded the Synthon inventors from asserting certain arguments made by them in favor of patentability in the course of the prosecution including, *inter alia*, that the compound of formula (3) was "new" and "novel";[26]

(v) the fact that Buscher reminded Hoorn and the named inventors about their duty of candor

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[25] *See Agfa*, 451 F.3d at 1378-79 (upholding a finding of inequitable conduct based on the failure to disclose information about prior art systems that, *inter alia*, had been the subject of "substantial documentation and internal discussions" between the inventors).

[26] *See Agfa*, 451 F.3d at 1378 (recognizing that "[t]his court has held that a trial court may infer deceptive intent based on a showing that a patentee withheld references with which it was intimately familiar and which were inconsistent with its own patentability arguments to the PTO").

in the course of the prosecution and repeatedly requested that they provide him with any and all information relevant to the pending patent applications, particularly any prior art that disclosed the chemical structure of the compound of formula (3);

(vi) the fact that every single one of the Synthon employees called to testify in this case claims not to have any recollection whatsoever of the SDD amlodipine page or the other internal Synthon documents disclosing Pfizer's use of the compound of formula (3) in its amlodipine production process; and

(vii) the fact that the jury found by clear and convincing evidence that Pfizer's invention "was communicated to one or more of the named inventors before the Synthon inventors made their invention,"[27] meaning the Synthon inventors knew about Pfizer's invention prior to their alleged conception of the invention claimed in the '481 and '738 patents.

In summary, it is the totality of all of the circumstances in this case that lead clearly and convincingly to a finding of deceptive intent on the part of Hoorn and the named inventors. Moreover, a balancing of this deceptive intent with the materiality of the misrepresentations and omissions involved here compels the conclusion that the '481 and '738 patents are unenforceable due to Synthon's inequitable conduct in the course of the prosecution. *See Agfa*, 451 F.3d at 1377 (stating that "[u]pon finding evidence that satisfies a threshold measure of materiality and intent, the trial court then weighs that evidence to determine that the equities warrant a conclusion of inequitable conduct"). Accordingly, Pfizer's inequitable conduct claim is properly granted and both patents in issue are deemed unenforceable.[28]

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[27] *See Synthon IP, Inc. v. Pfizer, Inc.,* 1:05cv1267 (E.D. Va. 2006) (Special Verdict Form).

[28] Neither reached nor decided is the question whether any additional derivative patents

An appropriate Order will issue.

/s/

Alexandria, VA
January 29, 2007

T. S. Ellis, III
United States District Judge

or patent applications are likewise unenforceable given Synthon's inequitable conduct in the course of the prosecution of the '481 and '738 patents.